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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,434	06/13/2006	Olivier Gerard	FR040033US	6582

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER	
GUPTA, VANI	
ART UNIT	PAPER NUMBER
3777	
NOTIFICATION DATE	DELIVERY MODE
03/02/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/596,434	GERARD ET AL.	
	Examiner	Art Unit	
	VANI GUPTA	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on 4/16/2010, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below. To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Tse Chen/

Supervisory Patent Examiner, Art Unit 3777

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1 – 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 1, it is unclear whether the recited structure, material, or acts are sufficient for performing the claimed function which would preclude application of 35 U.S.C. 112, sixth paragraph, because according to MPEP 2181, Section I:

> A claim limitation will be presumed to invoke 35 USC 112, sixth paragraph, **ONLY** if it meets the following 3-prong analysis:
>
> (A) the claim limitation **MUST USE** the phrase "means for" or "step for";
> (B) the "means for" or "step for" must be modified by functional language;
> (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material, or acts for achieving the specified function.

In the present instance, the claim limitations in Claim 1 each use the phrase "means for" or "step for", but each are modified by some structure, material, or acts recited in the claim. For example:

> ultrasound acquisition means for acquiring a three-dimensional ultrasound data set of said medical instrument using an ultrasound probe

does not meet the 3-prong test because the "ultrasound acquisition means for acquiring a three-dimensional ultrasound data set of said medical instrument" is being modified by additional structure "ultrasound probe" and

> means for converting said first localization of said region of interest within said referential of the X-ray acquisition means, using said localization of the ultrasound probe

does not meet the 3-prong test because the "means for converting said first localization of said region of interest within said referential of the X-ray acquisition means" is being modified by additional structure "using said localization of the ultrasound probe."

If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to:

(a) Amend the claim to include the phrase "means for" or "step for" in accordance with these guidelines: the phase "means for" or "step for" must be modified by functional language and the phase must not be modified by sufficient structure, material, or acts for performing the claimed function; or

(b) Show that the claim limitation is written as a function to be performed and the claim does not recite sufficient structure, material, or acts for performing the claimed function which would preclude application of 35 U.S.C. 112, sixth paragraph. For more information, see MPEP 2181.

If applicant does **not** wish to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to amend the claim so that it will clearly not be a means (or step) plus function limitation (e.g., deleting the phrase "means for" or "step for").

Claims 2 – 13 are also rejected for being dependent on Claim 1, which is rejected for improperly invoking 112-6th paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Hiam et al. (US 6,574,492 B1) in view of Chia et al. (6,233,477 B1) in view Asahina et al. (US 5,357,550).

Regarding Claim 1, Ben-Haim et al. (hereinafter Ben-Haim) suggests a medical system comprising:

a medical instrument (catheter #1) to be guided in a patient body (col. 3, ll. 3 – 5); and an

X-Ray acquisition means capable of acquiring a two-dimensional X-ray image of said medical instrument (col. 33, ll. 53 – 59).

Ben-Haim also suggests a second catheter (catheter #2) that is capable of acquiring a three-dimensional location/positional data set of said medical instrument (col. 13, ll. 4 – 6; and col. 23, ll. 28 – 40).

Ben-Haim also suggests that the catheter #2 may be localized or imaged by the X-ray acquisition means (col. 23, ll. 53 - 59); Ben-Haim is capable of providing localization of catheter #2 within a referential of said X-ray acquisition means.

Ben-Haim differs from Claim 1 in that Ben-Haim does not suggest that catheter #2 comprises an ultrasound acquisition means using an ultrasound probe (or transducer) to acquiring a three-dimensional location/positional (ultrasound) data set of said medical instrument,

Nonetheless, Chia et al. (hereinafter Chia) provides a dual-catheter system wherein one of the catheter tracks the position of the second catheter with the use of an ultrasound imaging transducer located on the first catheter (col. 2, line 39 – col. 3, line 3; col. 3, line 58 – col. 4, line 3; and col. 4, ll. 32 – 33 and 41 – 42).

Additionally, Asahina et al. (hereinafter Asahina)suggests that it is possible to provide a localization of said ultrasound probe within a referential of said X-ray acquisition means (Abstract; col. 2, ll. 49 – 53; and col. 5, ll. 37 – 40).

Furthermore, Ben-Haim in view of Chia is capable of selecting a region of interest around said medical instrument in the three-dimensional ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition means.

Furthermore, Ben-Hiam in view of Chia in view of Asahina is capable of converting said first localization of said region of interest within said referential of the ultrasound acquisition means into a second localization of said region of interest within said referential of the X-ray acquisition means, using said localization of the ultrasound probe, and capable of generating and displaying a bi-modal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization, as this only requires processor capabilites, which are disclosed by Asahina *("image processor,"* **(14)**), by Ben-Hiam *("computer," (51))*, and by Chia *("data acquisition computer,"* **(38)**).

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Ben-Hiam and Chia before one at the time the invention was made, to modify the x-ray-image-guided dual-catheter-positioning-system teachings of Ben-Haim with dual-catheter-positioning-system using ultrasound imaging teachings of Chia so that one could obtain optimal 3D localizing of the medical instrument (Chia: col. 4, line 9).

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Ben-Hiam in view of Chia and Asahina before one at the time the invention was made, to modify the x-ray-image-guided dual-catheter-positioning-system using ultrasound imaging teachings of Ben-Haim in view Chia of with the x-ray "radiographing" of an ultrasonic

probe of Asahina so that one could obtain additional information about the medical instrument by using a dual-imaging system (Asahina:col.5, ll. 31 – 55).

Regarding claims 2 – 5 and 9 – 13, Ben-Hiam in view of Chia in view of Asahina is capable of performing claimed functions as they only require the use of a processor, which is disclosed by Ben-Hiam, Chia, and Asahina, as discussed in the rejection of Claim 1 above.

Regarding claims 7 and 8, Ben-Hiam in view of Chia in view of Asahina suggests a system as claimed in claim 1, wherein said ultrasound probe is equipped with at least three non aligned and interdependent radio-opaque markers *("piezoelectric markers")* (see aforementioned citations of Chia) and said localization means are intended to localize said markers in at least a first 2D X-ray image having a first orientation angle in said referential (Asahina: col. 5, ll. 56 – 61 and col. 6, ll. 21 – 24); and wherein said localization means (via processor) are capable of further localize said markers in a second 2D X-ray image having a second orientation angle in said referential.

3. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Hiam in view of Chia in view Asahina) in view of Kockro (US PG Pub 2004/0254454 A1).

Regarding Claim 14, Ben-Haim in view of Chia in view of Asahina suggests a medical system comprising:

acquiring a two-dimensional X-ray image of said medical instrument using an X-ray acquisition system, acquiring a three-dimensional ultrasound data set of said medical instrument using said ultrasound probe and an ultrasound acquisition system, and localizing said ultrasound probe in a referential of said X-ray acquisition system (see rejection of Claim 1).

However, Ben-Haim in view of Chia in view of Asahina differs from Claim 14 in that Ben-Haim in view of Chia in view of Asahina does not suggest specifically selecting a region of interest of said medical instrument within said 3D ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition system.

Nonetheless, Kockro suggests selecting a region of interest (with use of a "bounding box") of a tracked medical instrument within a 3D image data set that define a first localization of said region of interest within a referential of the imaging system (paragraphs [0045 – 0046].

Ben-Haim in view of Chia in view of Asahina suggests converting said first localization within said referential of said ultrasound acquisition system into a second X-Ray localization within said referential of the X-ray acquisition system by virue of the fact that the ultrasound catheter probe is being tracked by the X-ray acquisition system (see rejection of Claim 1).

Ben-Haim in view of Chia in view of Asahina generating and displaying a bimodal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization (Asahin: col. 5, line 27 – col. 6, line 24).

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Ben-Hiam in view of Chia in view of Asahina and Kockrobefore one at the time the invention was made, to modify the x-ray-image-guided dual-catheter-positioning-system using ultrasound imaging with the x-ray "radiographing" of an ultrasonic probe teachings of Ben-Haim in view of Chia in view of Asahina with the bounding box teachings of Kockro so that one could obtain a more realistically" corresponding position of the medical instruemnt with respect to the corresponding imaging system (Kockro: paragraph [0046]).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Thursday (8:30 am - 6:00 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3777

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777